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February 4, 2002

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on the Pine Chemicals Association, Inc.'s HPV Test Plan and Robust Summary for Rosins and Rosin Salts

Dear Administrator Whitman:

The following comments on the Pine Chemicals Association, Inc.'s (PCA's) test plan for rosins and rosin salts are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

The PCA has formed an appropriate category. Rosins are naturally occurring substances found in pine trees and used commercially for printing inks, adhesives, chewing gums, coatings, soaps, and detergents. The PCA's test plan calls for two inappropriate animal tests: an aquatic toxicity test with fish and a developmental toxicity test. Conducting these two tests would result in the death of 300 animals.

This test plan violates the October 1999 Agreement among the EPA, industry, and health, animal protection, and environmental organizations, which state, in part:

1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.

8. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant.

As in its previous test plans for the tall oil fatty acids category and the tall oil and related substances category, the PCA is again proposing irrelevant aquatic toxicity tests on fish. We strongly recommend that the consortium replace this test with another method, such as ECOSAR or TETRATOX. Testing rosins on fish is especially inappropriate because their low solubility and lack of hydrolyzable functional groups hinder the ability to conduct aquatic tests. The PCA acknowledges the limitations of testing rosins in aquatic environments and therefore proposes to manipulate experimental conditions to enhance solubility. The PCA does

not describe how it intends to alter the OECD test guidelines, but does raise the possibility that the experimental conditions themselves "may cause non-specific toxicological effects." This confounds the experimental results and leads to difficulty in interpretation.

However, the PCA plans to perform water solubility analyses on five of the compounds in this category. To be consistent with the principles of thoughtful toxicology described in the October 1999 Agreement, the results of these solubility tests should be used to omit the fish test, if the results indicate, as expected, that these substances have low solubility. Nonanimal methods are available for studying aquatic toxicity, such as the ECOSAR, tests with algae, and the TETRATOX assay.

Rosins are well-known substances. Many experiments have already been conducted with rosin and hydrogenated rosin for acute and chronic endpoints. Repeat dose tests have been conducted in animals, and no adverse reproductive effects were observed.

These naturally occurring chemicals have been used for hundreds of years, and extensive human experience demonstrates that rosins do not appear to cause systemic toxic effects. They are regulated by the FDA as food additives and are used in beverages and as softeners in chewing gum.

Human experience shows that the main health concern from these chemicals is the potential for contact allergy, contact dermatitis, and occupational asthma. Research has been done on the kinetics and metabolism of rosins, and biomarkers have been identified. If the PCA would like further information about the potential adverse effects associated with these chemicals, occupational epidemiological studies would provide more relevant and meaningful data.

In conclusion, we recommend that the PCA eliminate its proposed aquatic toxicity and developmental toxicity tests with the naturally occurring rosins. Centuries of human experience indicate that the main health effects of concern are occupational dermatitis and asthma. The FDA already regulates these chemicals as food additives. Many animal toxicity and human observational studies have already been done with these substances. The fish tests are inappropriate due to the rosins' low solubility and lack of hydrolyzable functional groups, as well as the existence of viable, nonanimal methods. The two proposed tests will not change our understanding of these chemicals or change the way they are handled. In the spirit of thoughtful toxicology, these inappropriate, irrelevant tests should be omitted.

We are concerned that large numbers of fish are being killed in the HPV program, when established *in vitro* aquatic toxicity tests, such as TETRTOX, are available. Furthermore, some of the tests on fish that have been proposed are completely unnecessary given the physicochemical properties of some of the compounds. These concerns were described in a letter from the Physicians Committee for Responsible Medicine to Stephen Johnson dated December 5, 2001, and a letter from the People for the Ethical Treatment of Animals to Stephen Johnson dated January 18, 2002. We are still awaiting a response to this important issue.

Thank you for the opportunity to comment. I can be reached at 202-686-2210, ext. 302, or via e-mail at *ncardello@pcrm.org.* Correspondence should be sent to my attention at PCRM, 5100 Wisconsin Ave., N.W., Washington, DC 20016. I look forward to your response.

Sincerely,

Nicole Cardello, M.H.S.
Staff Scientist